UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. MARK THOMAS MOFFETT Defendant.	No. 18-cr-10249-WGY

GOVERNMENT'S TRIAL BRIEF

Defendant Mark Thomas Moffett ("Moffett") is charged with nine counts of wire fraud and six related counts of aggravated identity theft perpetrated in 2014 and 2015 when Moffett was a salesman in Illinois for Aegerion Pharmaceuticals, Inc. ("Aegerion"), which was based in Cambridge, Massachusetts.

The scheme concerns insurance coverage for Aegerion's cholesterol drug, Juxtapid, which cost over $25,000 per patient per month. Due to its high risk of liver toxicity, Juxtapid was subject to a "Risk Evaluation Mitigation Strategy" ("REMS") that, among other things, required a prescriber to enroll in the Juxtapid REMS program and to attest that the patient for whom he or she prescribed Juxtapid had a diagnosis consistent with a rare genetic disease, homozygous familial hypercholesterolemia ("HoFH"). The REMS also limited distribution of Juxtapid. It mandated that only one pharmacy could dispense the drug. That pharmacy would not dispense Juxtapid if a prescriber were not enrolled in the REMS program or had not signed a REMS attestation. Victim health insurance plans would not pay for Juxtapid for patients without a definite diagnosis of HoFH from the prescriber.

As alleged in the Second Superseding Indictment, Moffett falsely represented on

insurance forms and in insurance appeal letters that prescribing physicians had diagnosed their patients with HoFH, and he used the doctors' names and national provider identifiers ("NPIs") to carry out the fraud.

The trial is scheduled to begin on December 2, 2018, with testimony starting on December 3, 2019. The government expects its case to take approximately eight trial days, depending on the defenses presented and stipulations reached.[1]

I. BACKGROUND

This insurance fraud case occurred in the context of the Food, Drug, and Cosmetic Act violations to which Aegerion pleaded guilty before this Court in January 2018. *See United States v. Aegerion Pharmaceuticals, Inc.*, No. 17-cr-10288-WGY (D. Mass. 2017). Aegerion's criminal conviction was based on the marketing of Juxtapid for unapproved, medically unaccepted, off-label uses and in violation of the Juxtapid REMS program. This case will include evidence that Moffett misbranded Juxtapid consistent with Aegerion's corporate guilty plea, but the government will present the evidence only as an inextricably intertwined part of Moffett's insurance fraud scheme.

As alleged in the Second Superseding Indictment, Moffett was a salesman or "LSM" for Aegerion in central Illinois in 2014 and 2015. Moffett's territory included Springfield and Mattoon, where Moffett was familiar with, and often friends with, cardiologists, nurses, and medical office staff. None of the doctors in this case had patients whom they had diagnosed with HoFH; however, many of them had patients with high cholesterol and a history of heart disease who could not take statins due to painful side effects caused by statins.

[1] Assistant U.S. Attorneys Rachel Y. Hemani and Kriss Basil will represent the United States.

Moffett pitched Juxtapid to his cardiologist friends as a safe statin replacement for such patients. The physicians who received Moffett's marketing pitch prescribed Juxtapid for their "statin intolerant" patients. Moffett then took charge of, directed, and caused Juxtapid REMS forms, statements of medical necessity, and insurance forms to be submitted to insurance plans for coverage of Juxtapid that falsely represented that the prescribing doctors had prescribed Juxtapid for HoFH patients. Moffett also obtained fraudulent REMS forms from prescribers or obtained prescriptions from providers who had not treated relevant patients. Moffett also created and submitted fraudulent insurance prior authorization forms and appeal letters using prescribing physician's names and identifiers. The prior authorization forms and insurance appeal letters contained false information about patients. Evidence at trial will prove that insurance companies' decisions to cover Juxtapid was influenced by, and often determined by, whether a patient had a definite, documented diagnosis of HoFH.[2] Evidence at trial will also prove that the pharmacy would not submit a claim to an insurance plan if a prescriber was not REMS-enrolled and had not signed a REMS attestation. Evidence at trial will show that none of the patients at issue in the case had been diagnosed with HoFH by the physician who prescribed Juxtapid for them.

C. Witnesses

The government's witnesses include doctors who directly interacted with Moffett while Moffett was marketing Juxtapid, medical office staff who also interacted with Moffett, patients, health insurance personnel, and Aegerion personnel.

1. Medical Personnel and Patients

Drs. Amit Dande, Gregory Mishkel, Nilesh Goswami, Madhu Dukkipati, Amir Cheema,

[2] For example, the evidence at trial will be that federal regulations precluded Medicare Part D plans from covering Juxtapid for any diagnosis other than HoFH.

and Nasariah Nallamothu are cardiologists at a practice with offices in central Illinois, including in Springfield and Mattoon. The doctors are expected to testify that they did not knowingly participate in the Juxtapid REMS program and did not diagnose any of their patients with HoFH. The doctors are expected to testify that REMS forms, prior authorizations, and insurance appeals letters written in their names are fraudulent.

Allyson Gough and Marti Quinones work with Dr. Dande. They will testify regarding the Juxtapid forms for Dr. Dande's patient, GH. Quinones is expected to testify that she used false information at Moffett's direction on a prior authorization form.

Patient GH will testify that Gough, whose name is on his Juxtapid forms, did not provide medical treatment to him and that a signature on a patient health release form is fraudulent.

Tracy Shelabarger and Julia Santarelli were Dr. Mishkel's nurses. They are expected to testify that they completed Juxtapid forms with information provided to them by Moffett.

TC worked with Dr. Mishkel, but she was not his patient. She is expected to testify about her communications with Moffett about Juxtapid and about a prescription purportedly written by Dr. Mishkel.

Dr. Adeeb Ahmed is a cardiologist in Champlain, Illinois. He formerly worked in Springfield, Illinois. Dr. Ahmed is expected to testify that he prescribed Juxtapid for his statin intolerant patients, that he never has diagnosed any patient with HoFH, and that REM forms, insurance forms, and insurance letters written in his name are fraudulent.

Melinda Rees and Denise Vesper were nurses in Dr. Ahmed's office. Rees and Vesper are expected to testify regarding Moffett's completion of Juxtapid forms for Dr. Ahmed's patients.

Moffett socialized with the nurses in Dr. Ahmed's office. He used these relationships to gain access to the office and to perpetrate his insurance fraud.

The fraudulent insurance prior authorizations and appeal letters purporting to be from Dr. Ahmed contain the same handwriting as the forms that are the basis for charged counts. Dr. Ahmed and Ms. Vesper will identify the handwriting as belonging to Moffett. Moreover, the jury will be able to see for themselves that the handwriting matches known exemplars of Moffett's handwriting. Dr. Ahmed will further testify that he did not prescribe Juxtapid for patients with HoFH. Moffett pitched the drug to Dr. Ahmed as being for patients with high cholesterol who could not take statins because of side effects.

Finally, the government expects to prove that the loss amount attributable to Dr. Ahmed's patients was over $500,000. Dr. Ahmed and Denise Vesper's testimony is necessary in order for the government to prove the portion of the total loss amount attributable to their patients.

2. Aegerion Personnel

Richard Norton was an executive at Aegerion responsible for sales analytics. He will testify about the incentive compensation plan that Moffett participated in during 2014 and 2015.

Heather Rezendes was a manager of the COMPASS program at Aegerion and will testify about it operations and practices for handling insurance claims. She will explain business records generated by COMPASS personnel and will identify COMPASS personnel for the jury.

Mariel Lima was a COMPASS employee. She will testify that she used information that COMPASS received to try to obtain insurance coverage for one of Dr. Goswami's patients.

Sarah Whipple was Aegerion's Chief Compliance Officer. She will testify regarding Aegerion's compliance training of LSMs and about Aegerion's training of physicians as prescribers of Juxtapid. She will also testify about a compliance investigation of Moffett in January 2015, during which he admitted to writing an insurance appeal letter and denied knowledge of any other insurance appeal letters. She will testify that Moffett did not identify the

source of the letter as his supervisor. The insurance appeal letter at issue post-dated fraudulent letters for the charged counts and predated fraudulent letters in 2015.

3. Insurance Plan Representatives

Andrew Reudiger, Brian Wehneman, Amy Moyer-Carey, Erin McKenna, and Elizabeth Englehardt are representatives of health insurance plans, all of whom are expected to testify that a diagnosis of HoFH and the accuracy of clinical information submitted to the health plan was material to the health plans' coverage determination with respect to Juxtapid.

4. Others

Gary Sobocinski was an executive at Dohmen Life Sciences, the specialty pharmacy that dispensed Juxtapid. He is expected to testify about Dohmen operations.

Brendan Donlan is a Special Agent at the Federal Bureau of Investigation. He will publish documents admitted as business records or statements of the defendant.

II. CHARGES

A. Wire Fraud, 18 U.S.C. § 1343

The United States must prove the following elements beyond a reasonable doubt to convict Moffett of wire fraud:

> First, that there was a scheme, substantially as charged in the Indictment, to defraud or to obtain money or property by means of false or fraudulent pretenses;
>
> Second, that the scheme to defraud involved the misrepresentation or concealment of a material fact or matter, or the omission of a material fact or matter, or the scheme to obtain money or property by means of false or fraudulent pretenses involved a false statement, assertion, half-truth or knowing concealment concerning a material fact or matter;
>
> Third, that Mark Moffett knowingly and willfully participated in this scheme with the intent to defraud; and
>
> Fourth, that for the purpose of executing the scheme or in furtherance of the scheme, Mark Moffett caused an interstate wire communication to be used, or it

> was reasonably foreseeable that for the purpose of executing the scheme or in furtherance of the scheme, such a communication would be used, on about the dates alleged in Counts One through Nine.

18 U.S.C. § 1343.

B. Aggravated Identity Theft, 18 U.S.C. § 1028A(a)(1)

The United States must prove the following elements beyond a reasonable doubt to convict Moffett of aggravated identity theft:

> First, that Mark Moffett committed the corresponding count of wire fraud as charged in the Indictment.
>
> Second, that during and in relation to a corresponding crime of wire fraud, Mark Moffett knowingly transferred, possessed, or used a means of identification, here the name or the national provider identification number of a prescriber described in the Indictment, without lawful authority.
>
> Third, that the means of identification belonged to another person, here a doctor.
>
> Fourth, that Moffett knew the means of identification belonged to another person.

18 U.S.C. § 1028A(a)(1).

C. Willfully Causing the Act of Another, 18 U.S.C. § 2(b)

The United States intends to convict Moffett in part based on 18 U.S.C. § 2(b) and will seek a jury instruction consistent with the statute.

III. EVIDENTIARY ISSUES

A. Conduct Intrinsic to the Fraud Scheme

The government will present evidence of Moffett's off-label marketing of Juxtapid. His efforts to market Juxtapid for statin intolerant patients are inextricably intertwined with his efforts to defraud health insurance plans. Such evidence is not only a logical part of the story but also proves Moffett's intent and bad faith in submitting REMS forms and insurance materials

representing that patients had been diagnosed with HoFH.[3]

The government will also present evidence of Moffett's fraud scheme in operation at the office of Dr. Adeeb Ahmed. There are no charges pertaining to Dr. Ahmed's patients; however, Moffett's conduct at Dr. Ahmed's office was part of his scheme to defraud the victim insurance plans. Dr. Ahmed is also a victim of uncharged aggravated identity theft.

The fraud Moffett perpetrated at Dr. Ahmed's office is the same scheme as alleged in the second superseding indictment. Accordingly, the Court should admit the testimony of Dr. Ahmed, Ms. Rees, and Ms. Vesper. *See United States v. Sebaggala*, 356 F.3d 59.68 (1st Cir. 2001) ("Evidence of uncharged fraud activity that is substantially similar to the activity underlying a charged fraud scheme often is admitted to show knowledge or intent to defraud with respect to the charged fraud scheme.").

Alternatively, the evidence is admissible under Rule 404(b) because it proves Moffett's motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident. *United States v. Jambulat Tkhilaishvili*, 926 F.3d 1, 15 (1st Cir. 2019) (quoting Fed. R. Evid. 404(b)). In particular, the evidence establishes Moffett's efforts with Dr. Goswami and his colleagues was not anomalous. The handwriting on the forms shows the same person in charge of forms at a different practice, thus helping to identify the defendant as the perpetrator of the fraud. The methods and execution of the plan are similar. Moffett's pitch to the doctor and the resulting

[3] The government does not intend to offer evidence of Aegerion's corporate guilty plea to misbranding charges in January 2018 or of its contemporaneous False Claims Act settlement. However, to the extent that the defendant puts the legality of Aegerion's marketing of Juxtapid or of its handling of claims for Juxtapid, the government may ask the Court to take judicial notice of the guilty plea that this Court accepted from Aegerion and of the False Claims Act settlement. The government also notes that at least one of Dr. Ahmed's patients was a victim of the criminal case against Aegerion.

need to falsify insurance forms and letters demonstrates Moffett's motive and intent.

B. Handwriting Identification

The government intends to have lay witnesses and the jury identify handwriting, as allowed by Federal Rule of Evidence 901(b)(2).

C. Attorney-Client Privileged Information

When working as Aegerion's Chief Compliance Officer, Sarah Whipple reported to and took direction from Aegerion's inside and outside counsel. The United States does not intend, and will not seek, to elicit testimony that implicates Aegerion's attorney-client privilege.

The United States understands that Aegerion's outside counsel from Ropes & Gray LLP may attend trial during Whipple's testimony and may seek to be heard should questioning by the government or by defense counsel impinge on the corporation's privileges.

IV. OTHER ISSUES

A. Nullification Arguments

The United States will object to questions or arguments from the defendant that call for jury nullification. Specifically, the United States will object to any defense suggesting that the jury should not convict Moffett because other persons at Aegerion or in doctors' offices are *also* responsible for or participated in or benefited from Moffett's criminal conduct. That Moffett acted as part of a conspiracy or with accomplices is not a defense to the charged crimes.

As noted above, the government does not intend to offer evidence of Aegerion's criminal plea and False Claims Act settlement with the United States regarding the sales and marketing of Juxtapid. If the defendant claims, however, good faith based on Aegerion's corporate criminal conduct, the government will seek at least a corrective instruction from the Court.

Similarly, the government will object to questions or arguments aimed at jury bias against

insurance companies. Arguments from the defendant regarding the propriety or fairness of insurance coverage criteria can only serve the purpose of encouraging the jury to decide the case based on emotion rather than evidence and should thus be precluded under Federal Rule of Evidence 403.

B. Electronic Presentation of Evidence

With the Court's permission, the government intends to present its audio-visual and documentary evidence in electronic format using the Trial Director software. The government anticipates that a paralegal with the U.S. Attorney's Office will operate Trial Director.

C. Use of PowerPoint Presentation

With the Court's permission, the government intends to use PowerPoint presentations during its opening statements and closing argument, which will allow for a more organized presentation of the anticipated evidence and summation of the evidence in this case.

V. CONCLUSION

Although the foregoing does not exhaust all the issues that may be presented at trial, it is submitted to assist the Court and to present the government's positions on the above matters.

Respectfully submitted,

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United States Attorney

Dated: December 1, 2019 By: /s/Kriss Basil

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